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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,170	08/20/2001	Philippe Cinquin	CINQUIN-1	1102
7590 08/11/2004			EXAMINER	
Arthur L Plevy Duane Morris & Heckscher Suite 100 100 College Road West Princeton, NJ 08540			MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 08/11/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,170

Applicant(s)

CINQUIN ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed April 12, 2004. The Examiner acknowledges the amendments to the drawings, the amendments to the specification, and the amendments to claims 1-12. Claims 1-12 are pending.

On page 3 of the Amendment filed April 12, 2004, Applicant requests that the paragraph that begins on page 7, line 26 of the originally filed specification be replaced with a new paragraph that is not provided. Clarification is requested.

The Examiner further acknowledges the new Declaration filed June 9, 2004. The new Declaration is approved by the Examiner.

Drawings

2. The proposed drawing correction received on April 12, 2004 is approved by the Examiner.

Specification

3. The disclosure is objected to because of the following informalities: In line 2 of the paragraph beginning at line 16 of page 6 (as amended) "tat" should read --that--. Appropriate correction is required.

Claim Objections

4. Claim 7 is objected to because of the following informalities: in line 5, "including," apparently should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the trajectories in which the femur is displaced (see at least page 8, line 11-page 9, line 16), that several femoral positions are located with a marker and a triangulation system (see at least page 5, lines 21-32 and page 8, lines 8-10), how a constraint to the displacement of the center of rotation of the first femur is imposed without immobilizing the first femur (see at least page 6, lines 26-34), and types of calculation methods for determining a position of the center of rotation for which an optimization criterion is reached (see at least page 7, lines 3-22), does not reasonably provide enablement for the means by which the femur is displaced, how the triangulation system locates the femoral positions using only a marker disposed against the femoral condyles, how the positions are memorized, how the calculation methods are employed in the inventive method to determine the position of the center of rotation of the femur, and the structure of the calculation means of the apparatus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

With regard to the method step of “displacing said first femur,” the specification

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is not fully enabling because one skilled in the art cannot be certain whether the first femur is displaced by the test subject, a second party manipulating the femur of the test subject, or by a machine manipulating the femur of the test subject.

With regard to the method step of “locating several ones of said first femur’s positions,” although the specification states that the positions are located using a marker and a triangulation system, the specification is not fully enabling because it does not provide a full, clear and concise description of how the triangulation system is used in conjunction with the marker to locate the positions of the first femur. Instead the specification relies on the exemplification of an article referenced therein to disclose how the triangulation system is used. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Furthermore, “essential material” necessary to provide an enabling disclosure or describe the best mode of the claimed invention may not be incorporated by reference. See MPEP 608.01(p); *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

With regard to the method step of “memorizing said positions,” the specification is not fully enabling because one skilled in the art cannot be certain of the manner in which the positions are to be memorized. For example, the positions could be memorized in the mind of a test subject, the mind of a second party evaluating the test subject, recorded on video or in the triangulation system, or stored in the memory of a computer.

With regard to the method step of “searching a point linked to a referential of said

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first femur for which an optimization criterion taking into account said constraint is reached,” although the specification states that determining the position of the point is an optimization problem that may be solved using a variety of calculation methods disclosed in a variety of publications, the specification is not fully enabling because it does not provide a full, clear and concise description of how calculations are employed to determine the position of the point. No method steps for the various calculation methods are disclosed, particularly regarding how those calculation methods relate to the instant invention. Instead the specification relies on the exemplification of several articles referenced therein to describe the calculation methods. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Furthermore, “essential material” necessary to provide an enabling disclosure or describe the best mode of the claimed invention may not be incorporated by reference. See MPEP 608.01(p); *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). Additionally, the specification is not enabling as to how the constraint is accounted for in the method.

With regard to the apparatus limitation of “calculation means for searching a point linked to a referential of said first femur for which an optimization criterion taking into account said constraint is reached,” although the specification states that determining the position of the point is an optimization problem that may be solved using a variety of calculation methods disclosed in a variety of publications, as discussed hereinabove, the specification is not fully enabling because it does not provide a full, clear and concise description of how calculations are employed to determine the position of the point.

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Instead the specification relies on the exemplification of several articles referenced therein to describe the calculation methods. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Furthermore, "essential material" necessary to provide an enabling disclosure or describe the best mode of the claimed invention may not be incorporated by reference. See MPEP 608.01(p); *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). Additionally, the specification fails to set forth adequate disclosure of what is meant by the means-plus-function element recited in the claims such that equivalents of the claimed means cannot be determined. There is no disclosure in the specification of the structure required to perform the claimed function. Therefore, the specification is not fully enabling because one skilled in the art cannot be certain of the means by which the calculation methods are performed. For example, the calculation methods may be performed by a computer or by a second-party evaluator of the test subject.

Response to Arguments

7. Applicant's arguments, see pages 7-9 and 12-21, filed April 12, 2004, with respect to the objections to the drawings and the specification, the objection to claim 6, the rejections of claims 1-12 under 35 U.S.C. 112, second paragraph, and the rejections of claims 1 and 12 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the aforementioned rejections and objections have been withdrawn.

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8. Applicant's arguments filed April 12, 2004 regarding the rejections of claims 1-12 under 35 U.S.C. 112, first paragraph, have been fully considered but they are not persuasive. Applicant argues that claims 1 and 12 are fully described and enabled by the specification. The Examiner respectfully disagrees. As discussed in detail in paragraph 6 hereinabove, the specification is not fully enabling for all elements of the claimed invention. The specification does not disclose in a full, clear and concise fashion the claimed invention in a manner that enables one of ordinary skill in the art to make and use the invention. Applicant's arguments repeatedly point to references cited in the specification as providing examples that enable one having ordinary skill in the art to use the instant invention. However, the specification does not provide a full, clear and concise disclosure regarding how the calculation methods and other elements exemplified by the references cited therein relate to and are used with the memorized positions and the constraint of the instant invention. Moreover, it is improper to incorporate "essential material" in the specification by reference to a foreign application or to a publication; and "essential material" necessary to provide an enabling disclosure or describe the best mode of the claimed invention may not be incorporated by reference. See MPEP 608.01(p). Applicant also does not clearly define the structural elements forming the calculation means recited in claim 12, such that one having ordinary skill in the art could make the instant invention. The calculation means are not clearly illustrated in the drawing as amended, and the specification, while merely naming a plurality of calculation methods that can be employed in the instant invention, does not define any structural means or device for performing those calculation methods. In view of the foregoing, the

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specification of the instant application, is not fully enabling and the rejections of claims 1-12 under 35 U.S.C. 112, first paragraph, are maintained.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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July 26, 2004